

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSENDER FOR PATENTS PO Box 1430 Alexandria, Virginia 22313-1450 www.wopto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,214	09/19/2003	Wanda Richard	B-32686A/USN	7030
1095 7590 03/19/2008 NOVARTIS			EXAM	IINER
CORPORATE	E INTELLECTUAL PR	HELM, CARALYNNE E		
ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.	Applicant(s)	
10/667,214	RICHARD ET AL.	
Examiner	Art Unit	
CARALYNNE HELM	1615	

The MAILING DATE of this communication appears on the cover s Period for Reply	heet with the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPI WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COM.  Extensions of time may be available under the provisions of 37 CFR 1138(a). In no event however and the CS (c) MOXIFF from the mainly gaide of this communication.  Failure to reply with the think cause the application to Failure to reply within the set or extended period for reply will by statute, cause the application to	MMUNICATION.  ar, may a reply be timely filed  K (6) MONTHS from the mailing date of this communication.				
Any reply received by the Office later than three months after the mailing date of this communicatio earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on April 19, 2007.					
☐ This action is FINAL. 2b) ☐ This action is non-final.					
3) Since this application is in condition for allowance except for form	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
<ol> <li>Claim(s) is/are pending in the application.</li> </ol>	Claim(s) is/are pending in the application.				
4a) Of the above claim(s) is/are withdrawn from considerat	4a) Of the above claim(s) is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-16</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirem	ent.				
Application Papers					
9) The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in	abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the	drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the a	ttached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 L a) All b) Some * c) None of:	J.S.C. § 119(a)-(d) or (f).				
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No.					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a	1)).				
* See the attached detailed Office action for a list of the certified cop	ies not received.				
Attachment(s)					
	terview Summary (PTO-413)				

1)	М	Notice

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Information Disclosure Statement(s) (PTO/S5/08)

Paper No(s)/Mail Date \_\_\_\_\_.

5) Notice of Informal Patent Application 6) Other: \_\_\_\_\_.

Office Action Summary

Art Unit: 1615

#### DETAILED ACTION

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11 and 12 recite the limitation "said oil material" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claims, since each depend from claim 8, which does not claim a composition with an oil material.

Claims 7 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "from about 9,000 to about 14,000 cps" in claims 7 and 15 is a relative phrase, which renders the claim indefinite. The phrase "from about 9,000 to about 14,000 cps" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "from" typically indicates a minimum point, while the term "to" indicates a maximum point. However, the terms "from" and "to" are controverted by the term "about" which implies that values above and below 9,000 cps and 14,000 cps are permitted. Further, the extent of variance permitted by "about" is unclear in the context. Therefore it is unclear whether "about 9,000 cps" simply includes 8,000 cps and 10,000 cps or if it could also include any value between 1,000 and 13,000 cps as well. Similarly, it is

Art Unit: 1615

unclear whether "about 14,000 cps" simply includes 13,000 cps and 15,000 cps or if it could also include any value between 10,000 cps and 25,000 cps as well. Thus the interpretation of the phrase "from about 9,000 to about 14,000 cps" in this context is unclear as no definitive minimum and maximum for the range can be defined.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 5-10 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eriksen et al. (U.S. patent No. 6,043,202) in view of Chaussee et al. (U.S. Patent No. 4,478,853).

Eriksen et al. teach a shampoo composition, oil composition (pre-treatment), and method for treating cradle cap (seborrhea dermatitis) in infants and small children (see abstract; instant claims 1 and 8) Eriksen et al. also teach a kit that include shampoo. oil ore-treatment.

Art Unit: 1615

comb, sponge, brush and instructions for reducing or eliminating the condition of cradle cap (see column 4 line 66-column 11 line 10 and claim 20; instant claims 8-10, and 13). This kit is taught to include separate containers (cartons) of the shampoo and pre-treatment, along with the scale removal devices and instructions (see column 5 lines 1-3; instant claim 16). Eriksen et al. go on to teach a method for treating cradle cap (mitigating presence the of scales) where 1) the oil pre-treatment is rubbed (massaged) into the scalp, thereby loosening the scales, 2) a comb is used to remove the scales, and 3) the scalp is shampooed (see column 2 line 40-column 3 line 30, column 9, lines 25-40, and column 10 lines 7-10; instant claims 1-2 and 5). In addition, Eriksen et al. also teach that this process can be repeated as needed, indicating that a single performance of the process may leave some scales on the scalp surface. Eriksen et al. does not specifically teach a separate moisturizer being used in the method or included in the claimed kit.

Chaussee et al. teach a composition which imparts enhanced emolliency or moisturizing properties and provides extended protection against formation of dry, scaling skin or inhibiting scaling, flaking, drying and other causes of skin irritation (see column 2, lines 15-25 and column 3, lines 10-15). Chaussee et al. go on to teach particular components in this composition which include cocoa butter (see column 5, lines 65 and column 6, lines 5-65; instant claims 6 and 14) as well as the composition viscosity to be preferably from 2000 to 20,000 cps ((column 9, lines 25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the composition of Chaussee et al. to the composition of Eriksen et al. such that the kit would also include a moisturizer to be applied after the shampooing step. Since Eriksen et al. contemplated a situation where the scalp treatment process would need to be repeated (e.g. remaining scalp scales), it would have been obvious to employ an additional remedy that promotes removal of scales from skin and reduces the tendency of the skin to

Art Unit: 1615

scale. Application of a separate moisturizer after shampooing that performs these functions would therefore have been an obvious addition to the method of Eriksen et al. Furthermore, Chaussee et al. teach variations in the viscosity of the moisturizing composition of their invention, particularly between 2,000 cps and 20,000 cps (see column 9 lines 23-26). Instant claims 7 and 15 use the relative terminology "from about 9,000 to about 14,000 cps" which is not accompanied by any definition or explanation for the boundaries of the term "about" within the specification. Thus the teachings of Chaussee et al. meet the claimed limitation where 2,000 cps and 20,000 cps, as well as variations between them, are viewed as being within the boundaries of "from about 9,000 to about 14,000 cps". In addition, the viscosity of the moisturizing composition would have been well within the purview of a person of ordinary skill in the art at the time invention was made as a parameter to optimize as a matter of routine experimentation. Therefore claims 1-2, 5-10 and 13-16 are obvious over Eriksen et al. in view of Chaussee et al.

Claims 1-4 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eriksen et al. in view of Chaussee et al., Dahle (U.S. PGPub No. 2002/0039591), and DesLauriers et al. (U.S. Patent No. 5,221,534).

As discussed above, Eriksen et al. in view of Chaussee et al. make obvious a kit with an oil pre-treatment, shampoo, scale removing device, instructions, and moisturizer, as well as the method of use recited by instant claim 1 (see *Claim Rejections - 35 USC § 103* for claims 1-2, 5-10 and 13-16 above). Eriksen et al. in view of Chaussee et al. do not teach the use or mineral oil or gelled mineral oil, in particular, in the taught oil pre-treatment. Dahle teach topical compositions that are suitable for treatment of skin disorders and specifically name cradle cap as one such disorder (see paragraph 4 lines 1-2 and 6-7, paragraph 6; instant claims 1 and 8).

Art Unit: 1615

Within these compositions, Dahle teaches that mineral oil is included as a suitable and preferred ingredient (paragraph 7 lines 1-3; instant claims 3 and 11). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to employ mineral oil in the oil pretreatment taught by Eriksen et al. in view of Chaussee et al., to facilitate the treatment of cradle cap. Additionally, DesLauriers et al. teach gelled mineral oil for use in health and beauty aid compositions which give them desirable properties, more controlled consistency, and serve as a excellent vehicle for delivery to skin (abstract and column 2 lines 10-15, column 3 lines 8-23; instant claims 4 and 12). It therefore would have been obvious to one of ordinary skill in the art to use the gelled form of mineral oil taught by DesLauriers et al. in the oil pre-treatment taught by Eriksen et al. in view of Chaussee et al. and Dahle to take advantage of its physical properties in the composition. Further, since mineral oil in both the liquid and gelled form were known for their use in topical health/beauty aid compositions at the time of the invention, a person of ordinary skill would have had good reason to pursue them as options within their technical grasp and had a reasonable expectation of success. Therefore claims -4, 8 and 11 are obvious over Eriksen et al. in view of Chaussee et al., Dahle, and DesLauriers et al.

# Response to Arguments

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, sufficient suggestion to combine the prior art was present within the

references themselves as well as the general knowledge available to one of ordinary skill in the art. Nevertheless, these motivations have been elaborated in the rejections presented above.

### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/ Examiner, Art Unit 1615 /Michael P Woodward/ Supervisory Patent Examiner, Art Unit 1615